K121367
p1/4

JUN 2 1 2012

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Chuck Kolifrath
(978) 421-9786

Date Summary Prepared:

May 4, 2012

Device:

ZOLL Propaq XM

Classification: Class II

Cardiac Monitors – including Cardiotachometer and Rate Alarms (DRT)
Noninvasive Blood Pressure Measurement System (DXN)
Blood Pressure Computer (DSK)
Carbon Dioxide Gas Analyzer (CCK)
Oximeter (DQA)

Description:

The ZOLL X Series was cleared by the agency under 510(k) application K112432 as a multi-parameter monitor / defibrillator / external transcutaneous pacer with the following capabilities: 3, 5 and 12-Lead ECG, pulse oximetery, non-invasive blood pressure, invasive blood pressures, CO2, temperature, data recording and printing. The device is designed for use by trained medical personnel in both out-of-hospital and in-hospital applications. The proposed device (Propaq XM) is a monitor-only version of the cleared device. The Propaq XM is a configuration of the X Series device that depopulates the defibrillator/pacer and printer modules. All remaining features and functions of the two devices are identical and they share the same software code base.

Propaq XM Indications for Use:

The Propaq XM is intended for use by trained medical personnel who are familiar with basic monitoring, vital sign assessment, and the use of the Propaq XM. The Propaq XM is also intended for use by (or on the order of) physicians at the scene of an emergency or in a hospital emergency room, intensive care unit, cardiac care unit, or other similar areas of a hospital. The usage may be in an ambulance or at the scene of an emergency. It is also intended to be used during the transport of patients. The Propaq XM will be used whenever it is required to monitor any of those functions that are included (as options) in the device. The Propaq XM unit can be used on pediatric patients (as described in the following table) and on adult patients (21 years of age or older) with and without heart dysfunction.

Pediatric Patient Subpopulation	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age.
Infant	1 month to 2 years of age.
Child	2 to 12 years of age.
Adolescent	12 to 21 years of age.

ECG Monitoring

The Propaq XM is intended for use to monitor and/or record 3-, 5-, or 12-lead ECG waveform and heart rate, and to alarm when heart rate is above or below limits set by the operator. The patient population will range from newborn (neonate) to adult, with and without heart dysfunction.

Non-Invasive Blood Pressure Monitoring

The Propaq XM is intended for use to make non-invasive measurements of arterial pressure and heart rate, and to alarm if either parameter is outside of the limits set by the user. Measurements are made using an inflatable cuff on the patient's arm or leg. The patient population will range from newborn (neonate) to adult.

Temperature Monitoring

The Propaq XM is intended for use to make continuous temperature measurements of rectal, esophageal, or surface temperatures, and to alarm if the temperature is outside of the limits set by the user. The patient population will range from newborn (neonate) to adult.

SpO2 Monitoring

The Propaq XM pulse CO-oximeter, with Masimo Rainbow SET technology and the Rainbow series of sensors, is intended for use for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), and/or methemoglobin saturation (SpMet). The pulse CO-oximeter and accessories are indicated for use on adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, or in mobile environments.

Respiration Monitoring

The Propaq XM is intended for use to continuously monitor respiration rate and to alarm if the rate falls outside of the range set by the operator. Because the measurement method actually measures respiratory effort, apnea episodes with continued respiratory effort (such as obstructive apnea) may not be detected. It is not intended to be used as an apnea monitor. The patient population will range from newborn (neonate) to adult.

CO2 Monitoring

The Propaq XM is intended for use to make continuous noninvasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and breath rate. The patient population will range from newborn (neonate) to adult.

Invasive Pressure Monitoring

The Propaq XM is intended for use to display and make continuous invasive pressure measurements from any compatible pressure transducer. The primary intended uses are arterial blood pressure, central venous pressure and intracranial pressure monitoring. Any contraindications of the particular transducer selected by the user shall apply. The patient population will range from newborn (neonate) to adult.

12-Lead Analysis

The 12-lead ECG Analysis is intended for use in acquiring, analyzing and reporting ECG data, and to provide interpretation of the data for consideration by caregivers. The interpretations of ECG data offered by the device are only significant when used in conjunction with caregiver overread as well as consideration of all other relevant patient data. The 12-lead ECG Analysis is intended for use on adults (> 18 years of age).

Substantial Equivalence:

Propaq XM is substantially equivalent to the features and functions of the predicate X Series (K112432) reviewed and cleared by the FDA.

Comparison of Technological Characteristics

Propaq XM utilizes the same features and functions as X Series (K112432) reviewed and cleared by the FDA.

Performance Testing:

Extensive performance testing ensures that Propaq XM performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Conclusion

The information provided in this 510k demonstrates that the features and functions of the Propaq XM are substantially equivalent to those of the indicated commercially distributed unit with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2012

ZOLL Medical Corporation
c/o Mr. Charles Kolifrath
Regulatory Affairs Manager
269 Mill Road
Chelmsford, MA 01824-4105

Re: K121367
Trade/Device Name: ZOLL Propaq XM
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX, DXN, DQA, DPS, CCK, FLL
Dated: May 4, 2012
Received: May 7, 2012

Dear Mr. Kolifrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

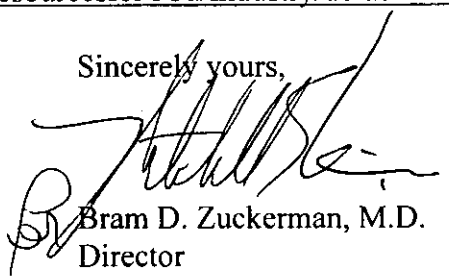
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **Propaq XM**

Indications For Use:

Propaq XM Indications For Use

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 6/21/2012

Division of Cardiovascular Devices

510(k) Number K121367

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(Division Sign-Off) 6/21/2012
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